Message

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IRIS meeting starts with high ambition, ends at familiar battle lines
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Kenneth Olden this week laid out a plan to achieve what his predecessors running EPA's National Center for Environmental Assessment could not, conducting more in-depth chemical risk assessments and getting chemical assessments out the door faster.

As expected, the "public stakeholder meeting" EPA convened on Tuesday to talk about the department's controversial Integrated Risk Information System (IRIS) was a big event. About 100 officials from the chemical industry, advocacy groups and other stakeholders, including many of the heavy hitters in the chemical assessment world, showed up at EPA's building in Crystal City, Va., for a chance to talk, one on one, with the EPA officials running the program.

Opening the gathering, Olden, appointed as the new director of National Center for Environmental Assessments about five months ago, promised to get the program back on track. "Our vision for IRIS can be summed up in one word, and that word is excellence. Excellence with respect to timeliness of the product, and excellence with respect to the quality of our product," he said. Olden aims to make IRIS a "shining example of good government at its best" and be "responsive to the needs and concerns of the American people."

The IRIS program has been the subject of significant critiques from the National Academy of Sciences and the Government Accountability Office, along with strong criticisms from industry groups.At Tuesday's meeting, key department officials were on hand to hear from all sides of the equation. Olden roamed the room before the start of the meeting, introducing himself to participants, and the meeting included multiple hours of agency officials taking direct questions and comments from the audience and through a webinar.

However, Olden, who held similar events when he was director of the National Institutes of Environmental Health Sciences, made clear that the meeting was not intended to be a "negotiation" or a "consensus building process," but rather a way to get input that will be considered as EPA implements changes to the program that were recommended in the influential 2011 National Academy of Sciences report on the draft assessment for formaldehyde. "[An] IRIS assessment is the responsibility of the Environmental Protection Agency, and we do not intend to delegate this responsibility to stakeholders," Olden said. With the NAS recommendations, EPA will not "go back and upend a whole assessment that is in process," a request frequently made by the chemical industry, he asserted.

Olden said EPA need feedback on five main issues. His ambition, he said, is to meet EPA Administrator Lisa Jackson's goal to complete IRIS assessments in 23 months, while also maintaining high quality.
The first issue was putting into place a "systematic review methodology" being developed by the National Toxicology Program that automatically finds relevant scientific studies and would help address claims that EPA "cherry picks" the data it uses for assessments, Olden said. The second issue was EPA's public engagement process, specifically how early in the process public comment should start and the number of opportunities for public comment. Olden said the EPA hopes to bring stakeholders early on in IRIS assessments to identify data gaps and other problems, hoping to avoid having to address complex problems 15 to 18 months into the process, and to possibly give industry two years of notice before beginning to assess a chemical to allow additional time to generate new data.
Third, EPA wanted to know ideas for how it might speed up the assessment process.
Fourth, EPA asked about how to implement "stopping rules," a point at which EPA would "close the scientific records and shut off the debate" in order to allow the agency to make scientific decisions.
Finally, EPA wanted to know ways to make public events more accessible to organizations without the resources to attend meetings in person.

Typical battle lines drawn again

However, when given the podium, industry and advocacy groups, while offering some specific suggestions and changes they'd like to see in how IRIS is run, at times retreated into familiar positions and talking points.
Advocacy groups accused the industry of foul play and needless delay, while industry groups maintained the need to take the time to make sure the exposure levels established through IRIS are scientifically defensible.

David Fischer, a senior director at the American Chemistry Council (ACC), said EPA needs to make the assessment process transparent and reproducible, to follow the NAS recommendations to make decisions

based on a weight of evidence, to allow the chance for meaningful stakeholder input, and to allow and be responsive to robust peer review. Fischer spoke of ACC's support for Rep. Ralph Hall's (R-Texas) scientific advisory board (SAB) reform bill, HR 6564, which would prevent EPA from excluding industry groups from SABs and limit the number of SAB members that could be receiving EPA grants.Fischer suggested that EPA should appoint a "referee, an honest broker" that would be tasked with assessing how EPA responded to public and peer review comments. He also repeated a longstanding request for all IRIS draft assessments in development, before being released, should be revised to include a weight of evidence approach, or for EPA to explain why it hadn't used a weight of evidence approach.

Richard Denison, a senior scientist at the Environmental Defense Fund who spoke alongside five other experts near the beginning of the meeting, said his main point was the need to "restore balance" the IRIS structure and practice, which in his view have been "badly tilted toward allowing one set of interests ... to wholly dominate over another equally critical set."
IRIS has "repeatedly allowed" demands for more data to indefinitely delay the completion of assessments, Denison said, making the average completion time for assessments to be 7.5 years, a delay that has "real-world consequences" of exposing the public to harm from chemicals. Scientific data is always incomplete and evolving, Denison said, so assessments should "in all but the most exceptional cases, be based on studies on hand." Denison called for "robust tracking" of IRIS from start to finish, with clear explanations from EPA when there is a delay, and fewer chances for public input, the large number of which, he says, allows industry to dominate the process. Denison said there should only be public comment once at the start of the assessment and once at the end.

Two experts from the public health sector and from a state environmental agency similarly called for EPA to streamline the IRIS assessment process, saying that delays have denied the public protection from chemical exposure. Gloria Post, a scientist at the New Jersey Department of Environmental Protection, gave the example of 1,2,3-trichloropropane, which was found to be a carcinogen in 1993, but the IRIS assessment wasn't updated until 2009, during which many were unaware of the cancer risk. Post said state officials frequently lack the resources to participate in public meetings on chemicals.

A question of trust

The meeting began to take on a more combative tone during a panel discussion and three-hour "open forum," when members of advocacy groups began to direct strong criticism toward the chemical industry.
The first shots of the night were arguably fired by Denison, during his opening remarks, when he accused the chemical industry of never showing any real interest in improving IRIS, saying the industry has put its financial interest above protecting public health. "There's a consistent pattern here, and it's time it's called out for what it is: A concerted and sustained effort by the chemical industry that is thinly veiled by its rhetoric, wrapping itself in terms like transparency and sound science," Denison said.
Other advocacy groups, at the meeting and submitting questions via the webinar, latched on to Denison's critique, making similar requests to EPA to level the playing field by not allowing industry groups to dominate the public comment process.

Pat Casano, government affairs counsel for General Electric, said EPA should "seriously consider" allowing industry to conduct its own risk assessments because of the difficulty of assessing the large numbers of chemicals in commerce. That suggestion prompted Jennifer Sass, a scientist from the Natural Resources Defense Council, to point out that EPA had already tried that a decade ago under the Bush administration for ethylene oxide and styrene, but the projects had been abandoned for costing more than doing the assessment in-house.
Sass also lobbed criticism at the ACC's support of HR 6564, the scientific advisory board reform bill, as being a chemical industry coordinated "attack on agency science and federally funded scientists in the academic community.

Chuck Elkins, president of the environmental consulting firm Chuck Elkins & Associates, agreed with a point advocacy groups made about a lack of trust around the IRIS program, which Elkins said "has gotten so bad it has threatened the sustainability of this program."
Elkins said some of industry's behavior was "stimulated by non-engagement, a policy of anti-engagement if I can be so bold, of certain people within the IRIS program," adding that industry's trust in IRIS could be restored through better engagement and a "trust but verify" appraoch.

When Fischer, of the ACC, made a comment about the need to put in place a third-party to ensure EPA adequately considers public comments, National Toxicology Program director Linda Birnbaum said it showed a lack of trust both in IRIS scientists conducting assessments and the peer reviewers. But Fischer countered that Birnbaum had made an "illogical statement," noting that, under Birnbaum's argument, there would be no point of peer review if everyone just assumes "IRIS got it right." The suggestion to add a third party would make sure "bias is checked by additional eyes," Fischer said.
"If it extends the process, well so be it. If we're not for ensuring that the value of IRIS assessments reaches a level that Dr. Olden would like it to reach, and that was what he said in his introductory remarks, I just think it's a goal worth exploring," Fischer said.

Speaking after the meeting, ACC spokesperson Scott Jenson said the trade group felt that advocacy groups "certainly cast all of the blames and the problems on us" but says he doesn't think that's the case.
"We've made it very clear that we think these assessments should be done in a timely fashion, but we agree with Dr. Olden in that quality and timeliness need to be the two driving factors, not one over the other, and we believe it can be accomplished," Jensen tells Pesticide & Chemical Policy. Jensen also said that ACC believes its proposals would actually speed up the process by addressing complicated issues up front.

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